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Award Number: DAMD17-00-1-0494

TITLE: Spirituality-based Intervention for African American Women with Breast Cancer

PRINCIPAL INVESTIGATOR: Diane R. Brown, Ph.D.

CONTRACTING ORGANIZATION: The University of Medicine and Dentistry
of New Jersey
New Brunswick, NJ 08903

REPORT DATE: September 2006

TYPE OF REPORT: Final Addendum

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

REPORT DOCUMENTATION PAGE

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
01-09-2006	Final Addendum	1 Jul 2003 – 1 Aug 2006

4. TITLE AND SUBTITLE

Spirituality-based Intervention for African American Women with Breast Cancer

5a. CONTRACT NUMBER

5b. GRANT NUMBER
DAMD17-00-1-0494

5c. PROGRAM ELEMENT NUMBER

6. AUTHOR(S)

Diane R. Brown, Ph.D.

E-Mail:

5d. PROJECT NUMBER

5e. TASK NUMBER

5f. WORK UNIT NUMBER

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)

The University of Medicine and Dentistry
of New Jersey
New Brunswick, NJ 08903

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)
U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSOR/MONITOR'S ACRONYM(S)

11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

Because social support has been shown to have value in decreasing morbidity and possibly in increasing length of survival in cancer patients, the objective of the study are: 1) to utilize a network of oncology services, churches, and community organizations to recruit African American women diagnosed with breast cancer for project participation; 2) to implement the spiritual-based intervention; 3) to assess the efficacy of the intervention to positively impact treatment-related outcomes; and 4) to refine the intervention for broader dissemination. The intervention involves and experimental/control group design approach. The experimental support group (Intervention group) will receive the Spiritual-based support intervention. There will be two control groups; control group A will include participants in a traditional support group model and control group B will include individuals who receive the standard care consisting of no additional structured support. An Advisory Committee comprised of breast cancer survivors and local clergy will provide guidance to project implementation. Data will be gathered through a pre-test at baseline (TI), a post test at the conclusion of the 7 months intervention (T2), and at a three month follow up at the end of the support group sessions (T3).

15. SUBJECT TERMS
Breast Cancer

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			USAMRMC
U	U	U	UU	27	19b. TELEPHONE NUMBER *(include area code)*

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INTRODUCTION

The research was designed to test a spiritual-based support group intervention for recently diagnosed African American breast cancer patients. It is hypothesized that the women who participate in the spiritual intervention will have a better quality of life, less depression, anger and anxiety, greater use of health promoting behaviors and a higher treatment compliance than the women in the two control groups. The two control groups consist of a traditional support group therapy and those patients who receive standard care with no additional structured support. A pre-test, post-test and follow up surveys are administered to all of the participants. The pre-test provides baseline data from which all the subsequent data can be compared and assessed. The post-test administered at the conclusion of the intervention tests how effective the intervention was on improving the overall quality of life of each participant. Finally, the follow-up survey administered three months after the end of the sessions tests the long-term effects of the intervention.

BODY

The research study was approved for funding by the Department of Defense (DOD) July in 2000 when the Principal Investigator was employed as a faculty member at Wayne State University. The project began in late September 2000 after requested changes to the protocol were finalized and approved by the Department of Defense and Wayne State University. A project advisory board was established in Detroit and a project team put in place to execute the project. Rounds one and two of the intervention were completed as previously reported. Round Three is incomplete.

In 2002, the Principal Investigator relocated from Wayne State University to the University of Medicine and Dentistry of New Jersey. This necessitated requesting and receiving approval of transfer of the grant, establishing a project infrastructure and building relationships in the community for participant recruitment. To date, one support group remains to be conducted. There have been several major difficulties which have delayed and hindered this project:

1) Transferring funds from Wayne State University to the University of Medicine and Dentistry (UMDNJ) due to the relocation of the Principal Investigator,
2) Establishing a project team and infrastructure
3) Obtaining IRB approvals at UMDNJ and DOD with numerous subsequent modifications and
4) Building relationships in the community to facilitate the recruitment of study volunteers

1) Transferring funds: There were innumerable difficulties in getting the funds transferred from Wayne State University to the University of Medicine and Dentistry of New Jersey. This process involved Wayne State preparing a final financial report. This required numerous phone calls and requests from the PI and other UMDNJ personnel. We also had to obtain the DOD sign-off on the transfer which occurred at a time when there were several changes in personnel with regard to the contact person for the grant. In addition, there were procedures and processing of necessary paperwork at UMDNJ.

2) Establishing project team and infrastructure: After the transfer was processed effective October 1, 2004, there was a delay in hiring Project Staff because a coordinator could not be hired until the monies were officially available at the University. In addition, the position had to be officially established through Human Resources, advertised and candidates interviewed in accordance with University procedures. This was another lengthy, time-consuming process.

Finally, we were able to hire Tamara Henry in March 2005. She was able to make some connections in the community as part of the recruitment process. However, her employment did not work out well and she separated from University service in September 2005. Again, we advertised the position and interviewed candidates in the fall of 2005. Dr. Joanne Fagan was subsequently hired to complete the project.

3) Obtaining IRB approval: The process of starting out new at UMDNJ and having to obtain IRB approval was arduous. Recruitment of study volunteers could not begin until all of the IRB approvals had been obtained. Even though the project protocols had been reviewed and approved by DOD and the Wayne State University IRB, we were required to go through the entire process again. This process was also a very extended one, involving several levels of approval and both the UMDNJ IRB and DOD. There were instances where agreement was lacking between the UMDNJ IRB and DOD on either the protocol, study consent or study forms. Again, this was a very laborious and time consuming effort.

4) Building relationships in the community to facilitate the recruitment of study volunteers. Establishing relationships in the community was viewed as an important aspect of subject recruitment. Once funds were transferred, an Advisory Committee was identified comprised of breast cancer survivors and local clergy. The Advisory Group has met and support group facilitators were also identified. A variety of recruitment strategies were implemented including: 1) distribution of study recruitment flyer by staff at local cancer centers (n=6); 2) placement of study recruitment flyer at local pharmacies (n=30); 3) placement of study recruitment flyers throughout UMDNJ; 4) placement of study recruitment flyer in local hair salons (n=169); 5)

distribution of study information to health and women's ministries of local churches (n=17); and 6) distribution of a press release. All of these methods yielded minimal results (3 calls from potential subjects, 2 of which were eligible and agreed to participate). We finally began to recruit subjects directly from the Oncology Department at UMDNJ – NJ Medical School when they came for a treatment or follow-up visit. Prior to talking with the patient, the staff person would discuss the project with them and ask if they were willing to talk with us. If they said yes, we screened them for eligibility. Over a five month period 11 women were screened for eligibility of which 8 were eligible and agreed to participate. Because of the slow pace of recruitment we realized that were would not be able to meet the goal of recruiting and randomizing 54 women.

Reviewing the data from the two rounds of the intervention from Wayne State demonstrate the following distribution in the three study arms: Traditional (n=10), Spiritual (n=17) and Standard (n=4). Although our recruitment efforts at UMDNJ were extensive, our yield was small (n=8). The stage of disease and age are shown in Table 1. After putting forth the effort to find these 8 eligible women and noting the distribution from Wayne State is not balanced, we plan to only enroll these women in the standard arm and administering the baseline and follow-up questionnaires.

Table 1

Stage of Diagnosis	**I**	**II**	**III**
	4 (50%)	2 (25%)	2 (25%)
Age	**40-49**	**50-59**	**60-65**
	2 (25%)	5 (62.5%)	1 (12.5%)

Spiritual-Based Counseling for African American Women with Breast Cancer
Recruitment Summary

Hospitals/Medical Centers

Breast center	Mountainside Breast Cancer Program	Recruitment flyers distributed 1/27/06	Yielded no calls
Women's Health	Mountainside Women's Health Center	Recruitment flyers distributed 1/27/06	Yielded no calls
Women's Health	Clara Maass Women's Health Center	Recruitment flyers distributed 1/27/06	Yielded no calls
Hematology/Oncology	Essex Hematology Oncology at Clara Maass	Recruitment flyers distributed 1/27/06	Yielded no calls
Radiology	Clara Maass Medical Center	Recruitment flyers distributed 1/27/06	Yielded no calls
Imaging Center	Progressive Imaging Center at Clara Maas	Recruitment flyers distributed 1/27/06	Yielded no calls
Family Care Center	St. James Hospital	Recruitment flyers distributed 2/08/06	Yielded no calls
	St. Michael's Medical Center		
Breast center	The Connie Dwyer Breast Center	Recruitment flyers distributed 2/15/06	Yielded no calls
Regional Cancer Center	St. Michael's Medical Center	Recruitment flyers distributed 2/15/06	Yielded no calls
	University of Medicine & Dentistry		
Breast center	Center for Breast Imaging	Recruitment flyers distributed 2/3/06	Yielded no calls
Radiology	Columbus Hospital	Recruitment flyers distributed 2/02/06	Yielded no calls
Center for Oncology	Columbus Hospital	Recruitment flyers distributed 2/02/06	Yielded no calls
Registry office	Columbus Hospital	Recruitment flyers distributed 2/02/06	Yielded no calls
		Recruitment flyers distributed 2/08/06	Yielded no calls
Oncology	Newark Beth Israel Medical Center	4/5/06 informed they could no longer help	
	Flo Okin Oncologic Center	Recruitment flyers distributed 2/08/06	
Radiology	Newark Beth Israel Medical Center	4/5/06 informed they could no longer help	Yielded no calls
Cancer Center	St. Barnabas Medical Center Cancer Center	Declined to participate	

UMDNJ

We have posted numerous study flyers throughout UMDNJ and this has only yielded 1 call. This patient was screened, is eligible and agreed to participate.

In April 2006, we began actively recruiting women through UMDNJ's cancer outpatient program. The nurse practitioner each Monday lets us know when women who fit our criteria will be coming in for appointments during that week. We go to the clinic and the nurse practitioner first talks with the women, explains the study and gets their verbal approval to talk with us. If the patient is willing to talk with us, she is screened and if eligible told about the study. This method has yielded 6 potential participants over 5 months.

Physicians

Dr. Said Saleh	Clara Maass	Recruitment flyers distributed 1/27/2006	Yielded no call
Dr. Hemalatha Vasireddy	Clara Maass	Recruitment flyers distributed 1/27/2006	Yielded no call
Dr. John Conti	Clara Maass	Recruitment flyers distributed 1/27/2006	Yielded no call
Dr. Alan Lippman	Clara Maass	Recruitment flyers distributed 1/27/2006	Yielded no call
Dr. James M. Orsini	Clara Maass	Recruitment flyers distributed 1/27/2006	Yielded no call
Dr. Patrick DiPaolo	Mountainside	Recruitment flyers distributed 1/27/2006	Yielded no call
Dr. Robert Zager	Mountainside	Recruitment flyers distributed 1/27/2006	Yielded no call
Dr. Charles Sagorin	Mountainside	Recruitment flyers distributed 1/27/2006	Yielded no call
Dr. Eric Whitman	Mountainside	Recruitment flyers distributed 1/27/2006	Yielded no call
Dr. Michael Kane	Mountainside	Recruitment flyers distributed 1/27/2006	Yielded no call
Dr. Nancy Elliot	Mountainside	Recruitment flyers distributed 1/27/2006	Yielded no call
Dr. Kathleen Ruddy	Clara Maass	Recruitment flyers distributed 1/27/2006	Yielded 1 call
Dr. Nadine C. Pappas	Clara Maass	Recruitment flyers distributed 1/27/2006	Yielded 1 call
Dr. Margarette R.N. Bryan	UMDNJ	Recruitment flyers distributed 2/3/2006	Yielded no call
Dr. Alice Cohen	Beth Israel	Recruitment flyers distributed 2/8/2006	Yielded no call

Mammography Centers

New Jersey Open MRI	Newark	Recruitment flyers distributed 2/20/2006	Yielded no calls
South Mountain Imaging Center	Milburn	Recruitment flyers distributed 2/20/2006	Yielded no calls
Montclair Radiology	Montclair	Recruitment flyers distributed 2/20/2006	Yielded no calls
St. James Hospital Diagnostic Radiology	Newark	Recruitment flyers distributed 2/20/2006	Yielded no calls
UMDNJ-Imaging Center	Newark	Recruitment flyers distributed 2/20/2006	Yielded no calls
Progressive Imaging Center at Clara Maas	Bellville	Recruitment flyers distributed 2/20/2006	Yielded no calls
Magnetic Resonance of NJ, P.A.	Nutley	Recruitment flyers distributed 2/20/2006	Yielded no calls
Montclair Radiology Associates, P.A.	Nutley	Recruitment flyers distributed 2/20/2006	Yielded no calls
North Essex Imaging	Newark	Recruitment flyers distributed 2/20/2006	Yielded no calls
St. Joseph's Hospital and Medical Center	Patterson	Recruitment flyers distributed 2/20/2006	Yielded no calls
St. Barnabas Outpatient Center	Livingston	Recruitment flyers distributed 2/20/2006	Yielded no calls
St. Joseph's Regional Med. Ctr. Ambulatory Imaging Ctr.	Clifton	Recruitment flyers distributed 2/20/2006	Yielded no calls
Clifton Medical Center	Clifton	Recruitment flyers distributed 2/20/2006	Yielded no calls
Clifton Medical Imaging Center	Clifton	Recruitment flyers distributed 2/20/2006	Yielded no calls
Diagnostic Imaging of Clifton, P.A.	Clifton	Recruitment flyers distributed 2/20/2006	Yielded no calls
Allwood Imaging	Clifton	Recruitment flyers distributed 2/20/2006	Yielded no calls

Churches

Contacted	Health Ministry	Women's Ministry	Faxed Information	Mailed Information	Emailed Information	Follow-up	Presentation scheduled	
17	6	14	11	5	1	3	3	Yielded no subjects

Although churches voiced an interest, making contact with either the head of the Health or Women's Ministry group was difficult. It was difficult because we could not get phone contact information for the group leaders due to the fact that it was their home number and church leaders were not willing to give that out. They would pass our information on but it would dead end there even with repeated calls/faxes.

Pharmacies

We contacted pharmacies in Newark, East Orange, Irvington, Bloomfield and Montclair asking permission to hang our study flyer.

Contacted	Agreeing to post flyer	Flyers posted	
50	27	27	Yielded no calls

Media

- Television
  - Cablevision local channel programming
    Dr. Brown taped a PSA 12/16/05 which aired in February
    Yielded no calls

- Press release
  - UMDNJ media relations staff Kaylyn Dines produced a press release (DOD IRB approved UMDNJ IRB approved)
  - UMDNJ media relations staff Kaylyn Dines distributed press release in early March.
    Received one call from a woman who read about the study in her Local Talk Newspaper. She was eligible and agreed to participate

- Magazines

  - UMDNJ media relations staff Kaylyn Dines got *Positive Community*, a church and community magazine to print a half page story about the study.

    - Yielded no calls

Hair salons

- Mail flyer to hair salons requesting them to post it in their place of business.

Location of Salons	Number mailed	Number returned	Number posted	When mailed	
Newark	105	18	87	2/9/2006	Yielded no calls
East Orange and Orange	28	7	21	2/13/2006	Yielded no calls
Irvington	81	20	61	2/13/2006	Yielded no calls
Total	214	45	169		

Key Research Accomplishments and Reportable Outcomes

Among the accomplishments has been the establishment of relationships with various community organizations as well as with the staff of the Cancer Center at the New Jersey Medical School. These relationships are necessary for the recruitment of volunteers for research studies. We have also recognized that different that the target population of African American breast cancer patients was considerably more dispersed than in Detroit where there were fewer cancer treatment facilities than in the Greater Newark- New York City area. This necessitated embarking upon a variety of recruitment strategies. During the 18 months of actual program operation in Newark we were able to recruit eight African American women who met the study criteria.

Conclusions

From the previous rounds of the intervention, we have reported that overall, the spiritual group participants appear to be more responsive to participating in the support group than are those in the traditional group. The members are much more lively and excited to be there than the traditional group members. The spiritual group members interact much more with each other than do the traditional group members who are more reserved. The spiritual group has better attendance by the participants compared to the traditional group. The women in the spiritual group tend to mention spiritual issues on a much greater frequency than the women in the other group. In addition, with regard to recruitment of African America breast cancer patients, strategies are most successful when collaboration is obtained from the physicians and their staff.

References

Appendices

Breast Cancer Advisory Committee Meeting

August 12, 2005

5:30pm

Introduction

- Welcome
- Role of Advisory Committee
  - Offer guidance and suggestions in recruitment
  - Attend bimonthly meetings for general progress of the study in October 2005, January 2006 and March 2006

Purpose of the Study

- To utilize a network of Oncology services, churches, and community organizations to recruit African American women w/ breast cancer for participation in a support group intervention

Purpose of the Study cont'd

- To implement the Spiritual-based intervention
- To assess the efficacy of the intervention to positively impact treatment-related outcomes
- To refine the intervention for broader dissemination

Hypotheses

- Women in the spiritual-based intervention will have less depression, anger, and anxiety than women who are in control groups
- Women in the spiritual-based interventions will have greater overall quality of life than women who are in control groups

Hypotheses cont'd

- Women in the spiritual-based intervention will have greater use of health promoting behaviors than those who are in control groups
- Women in the spiritual-based intervention will have greater treatment adherence than those who are in control groups

RECRUITMENT CRITERIA

- Recruit at least 50 African American women who were diagnosed with breast cancer within 24 months at stage 1, 2, or 3
- African American women must be between the ages of 40 and 65 years of age
- Co-Morbidities will be excluded (ie Heart conditions, Diabetes, etc)

Recruitment Strategy

- Meet with Advisory Board to discuss information dissemination and how group should be marketed
- Contact Kaylin Dines to put the study in the newsletter
- Contact other media outlets that target African American Women (98.7FM, etc)

Recruitment Strategy cont'd

- Complete Mass mailing to all area churches and health centers week of 8/12/05
- Contact and meet with Sisters Network of Essex County (8/16) and Central NJ
- Contact and meet with clergy members and obtain referrals
- Complete eligibility screening by 9/21/05

Next Steps

- Recruit at least 50 women who meet the criteria
- Meet with the Interviewer to arrange pre-test schedules
- Tentative meeting dates for committee-Suggestions
- Schedule date(s) for trainer to come to NJ to meet facilitators
- Times and Dates have been set to begin support groups October 4-November 29

Prospective Facilitators

Barbara Howard, RN
806 Wood Ave
Colonia, NJ 07067
732-499-6731

Brenda Gibson, Health Educator
360 Academy St
South Orange, NJ 07079
bgibson@sbhcs.com
973-926-7884

Tracey Jenkins, RN
737 Coolidge St
Plainfield, NJ 07062
908-222-0641

Pat Wrazz
Macedonia Baptist Church
78 Monticello Ave
Newark, NJ 07106

UMDNJ
SCHOOL OF PUBLIC HEALTH
University of Medicine & Dentistry of New Jersey

Institute for the Elimination of Health Disparities

Spiritual-Based Counseling for African American Women with Breast Cancer

Principal Investigator: Diane R. Brown, Ph.D.
Institute for the Elimination of Health Disparities

Consent Form

This consent form is part of an informed consent process for a research study and it will give information that will help you understand what the study is about and what will happen in the course of the study.

If you have questions at any time during the research study, you should feel free to ask them and should expect to be given answers that you completely understand.

After all of your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

The study doctor, Dr. Diane R. Brown, or another member of the study team (an investigator) will also be asked to sign this informed consent. You will be given a copy of the signed consent form to keep.

You understand that you are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

Sponsor of the study:

United States Department of Defense is the sponsor of this research study. The study doctor is being paid to conduct this study according to a budget that will cover the costs of the study. The costs that are usually covered include things such as: physical examinations, laboratory tests required by the study, and the costs of collecting all of the information required by the study.

Why is this study being done?

You are being asked to take part in a research study that is designed to gather information about whether spiritual counseling may improve quality of life issues for African American breast cancer survivors. The research study is being conducted at UMDNJ-School of Public Health and is being sponsored by the U.S. Department of Defense (DOD).

65 Bergen Street, Room 1346 • PO Box 1709, Newark, NJ 07101-1709
Phone: 973-972-4382 • Fax: 973-972-4403 • Web Site: www.umdnj.edu

Why have you been asked to take part in this study?
You have been asked to participate in this study because you have been diagnosed with breast cancer and you are an African-American female, which are the criteria for enrolling in this study.

Who may take part in this study? And who may not?
Female African-American breast cancer patients between the ages of 40 and 65 may participate in this study. Potential volunteers will be screened to determine if they meet the eligibility requirements to take part in this study.

How long will the study take and how many subjects will participate?
You have been informed that the study will take place over a ten month span.

54 subjects will be enrolled in the study.

What will you be asked to do if you take part in this research study?
If you are selected to the standard care only group, you will complete interviews at three time periods, one at the beginning of the study that will take about one hour, the second seven months later, and a third three months later that will take about 30-45 minutes each. If you are selected to the spiritual-based or traditional support groups, you will complete the interviews and will also participate in seven discussion sessions, over a four month period, lasting about one hour and 30 minutes each.

You will also be asked to participate in pre-study and post-study interviews. You will be asked to complete a questionnaire which will have questions pertaining my socio-economic status, demographic information, your spiritual well-being, help seeking and decision making, and healthcare accessibility.

What are the risks and/or discomforts you might experience if you take part in this study?
We do not expect any injury; however you may feel some discomfort when facing issues related to your cancer or to your spiritual beliefs at a time when you are dealing with your illness. Each support group will be assigned two staff persons who are professionally trained in working with cancer support groups. The staff will be available for individual counseling if needed.

Are there any benefits if you choose to take part in this research study?
There may be no direct benefit to you for taking part in this study; however your participation may benefit you in coping with your cancer diagnosis.

What are your alternatives if you don't want to take part in this study?
You have a choice not to take part or to participate in this study. You can also take part in a regular breast cancer support group if you wish.

How will you know if new information is learned that may affect whether you am willing to stay in this research study?
You will be informed by the Study Doctor or staff when new information is learned that may affect whether you are willing to stay in this research study.

Who will be allowed to look at your research records from this study?

In addition to key members of the research team, the following people will be allowed to inspect parts of your research records related to this study:

- The Institutional Review Board (a committee that reviews research studies)
- Officials of the University of Medicine and Dentistry of New Jersey
- The study sponsor Department of Defense
- Department of Health and Human Services (DHHS) (regulatory agency that oversees human subject research)

By taking part in this study, you should understand that the study collects demographic data and data on your health. This data will be reported to the University of Medicine and Dentistry of New Jersey who will store and process your data with electronic data processing systems. The data will be kept for six years.

Your personal identity, that is your name, address, and other identifiers, will be kept confidential. You have a code number and your actual name will not be used. Only your study doctor will be able to link the code number to your name and will keep this information for six years. A breach of confidentiality is a risk; however we make every possible effort to ensure that data will not be released to anyone outside of the study.

Your data may be used in scientific publications. If the findings from the study are published, you will not be identified by name. Your identity will be kept confidential. The exception to this rule will be when there is a court order or when a law exists requiring the study doctor to report communicable diseases. In this case, you will be informed of the intent to disclose this information to the state agency. Such a law exists in New Jersey for diseases such as cancer, infectious diseases such as hepatitis, HIV, viruses and many others.

The Department of Defense will be allowed to examine the data in order to analyze the information obtained from this study, and for general health research.

In applications for marketing authorization, your data may be submitted to domestic and foreign drug regulatory agencies.

If you do not sign this approval form, you will not be able to take part in this research study.

You can change your mind and revoke this approval at any time. If you change your mind, you must revoke my approval in writing. Beginning on the date you revoke your approval, no new personal health information will be used for research. However, researchers may continue to use the health information that was provided before you withdrew your approval.

You have the right to look at your study data at your study doctor's office and to ask for corrections of any kind to any of your data that is wrong.

Will there be any cost to you to take part in this study?
There will be no cost to you to take part in this study.

Will you be paid to take part in this study?
You will receive a total of $70.00 for taking part in this study according to the following schedule:

Control Group A:
- $20.00 for completing the initial interview
- $20.00 for completing the post interview
- $30.00 for the completion of a follow up interview

Control Group B:
- $20.00 for completing the initial interview
- $20.00 for completing the post interview
- $30.00 for the completion of a follow up interview

Intervention Group:
- $20.00 for completing the initial interview
- $20.00 for completing the post interview
- $30.00 for the completion of a follow up interview

You must complete all of the interviews to receive the full $70.00. Otherwise, you will be paid only for the interviews you complete.

What will happen if you are injured during this study?
There is no risk of injury in this study.

What will happen if you do not wish to take part in the study or if you later decide not to stay in the study?
Participation in the study is voluntary and you are free to withdraw at any time. If you decide to withdraw from the study, you will continue to receive standard care. Also, if you are uncomfortable with a question on the questionnaire, you are free to leave it unanswered.

Who can you call if you have any questions?
If you have any questions concerning your participation in this study now or in the future, Diane R. Brown, Ph.D., Principal Investigator, or one of her associates can be contacted at (973) 972-4382. If you have any questions regarding your rights as a research subject, you can contact the Director or Chair of the Institutional Review Board at (973) 972-3608.

What are your rights if you decide to take part in this research study?
You understand that you are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

You understand that you have the right to ask questions about any part of the study at any time. You understand that you should not sign this form unless you have had a chance to ask questions and have been given answers to all of my questions.

You have read this entire form, or it has been read to you, and you understand what has been discussed. All of your questions about this form and this study have been answered.

You agree to take part in this research study.

Subject Name:

_____

Subject Signature:

_____ Date: _____

Investigator Signature:

_____ Date: _____

Are you an African American woman, between the age of 40 and 65, diagnosed with Breast Cancer within the past 2 years ?

IF YOU ANSWERED YES, please join our study which offers a **FREE Support Group for African American Women with Breast Cancer**

The **BENEFITS** of joining this group:

- Talk to other Breast Cancer survivors and listen to their stories of hope
- Receive social support for living with Breast Cancer
- Get reimbursed for your travel and time
- Refreshments will be served at meetings
- Receive the latest breast cancer research information, as a result of your participation

In addition to the support group you will be asked to complete 3 interviews *(between 30-45 minutes each)*

For further information, please contact us at: (973) 972-4382

Principal Investigator:
Diane Brown
Executive Director
UMDNJ – Institute for the Elimination of Health Disparities
65 Bergen Street, Suite 1346
Newark, NJ 07101

(973)972-4382 (973)972-4382 (973)972-4382 (973)972-4382 (973)972-4382 (973)972-4382 (973)972-4382 (973)972-4382 (973)972-4382 (973)972-4382 (973)972-4382 (973)972-4382 (973)972-4382 (973)972-4382

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Principal Investigator:
Diane Brown
Executive Director
UMDNJ – Institute for the Elimination of Health Disparities
65 Bergen Street, Suite 1346
Newark, NJ 07101

Are you an African American woman, between the age of 40 and 65, diagnosed with Breast Cancer within the past 2 years ?

IF YOU ANSWERED YES, please join our study which offers a FREE Support Group for African American Women with Breast Cancer

The BENEFITS of joining this group:

- Talk to other Breast Cancer survivors and listen to their stories of hope
- Receive social support for living with Breast Cancer
- Get reimbursed for your travel and time
- Refreshments will be served at meetings
- Receive the latest breast cancer research information, as a result of your participation

In addition to the support group you will be asked to complete 3 interviews (between 30-45 minutes each)

For further information, please contact us at: (973) 972-4382 or complete the form below.

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65 Bergen Street, Suite 1346
Newark, NJ 07101

Complete and give to nurse/technician

First name: _____ **Last name:** _____

Address: _____

City: _____, **State:** _____ **Zip code:** _____

Telephone number: ( ) _____

Best time to reach you at above number: _____

A representative of the study will contact you to explain the study in more detail.

UMDNJ-School of Public Health

Researchers at UMDNJ Seek African-American Women for Breast Cancer Clinical Trial

NEWARK - Researchers at the University of Medicine and Dentistry of New Jersey are seeking African-American women who have breast cancer for a randomized study that is designed to measure the impact of group therapy on quality of life. The seven-week study, conducted by researchers at the Institute for the Elimination of Health Disparities at the UMDNJ-School of Public Health in Newark, will also identify the value that spiritual group counseling has on treatment compliance.

"Research shows that African-Americans are more likely than Caucasians to use spirituality and religious involvement when coping with adversity," said Dr. Diane Brown, executive director of the Institute for the Elimination of Health Disparities. "Through this study, we will test the efficacy of a culturally tailored, non-denominational counseling group's ability to improve the psychological well being and quality of life of African-American women with breast cancer."

A total of 54 African-American women between the ages of 40 to 65, who have been diagnosed with stage I, II, or III breast cancer within the past two years, are being recruited for the study. Each participant will be randomly assigned to one of three study groups. Members of the first group will focus on spirituality and participate in seven weekly group sessions at the UMDNJ-University Hospital in Newark. In addition to opening and closing the sessions with prayer, a minister and a nurse will facilitate the sessions on topics such as communication, stress management, grief counseling, intimacy, sexuality, goal setting and fitness.

Women in the second group will focus on traditional support group activities that will be facilitated by a health educator and a nurse. The third group, the standard care group, will be instructed to follow their prescribed medications without support group involvement.

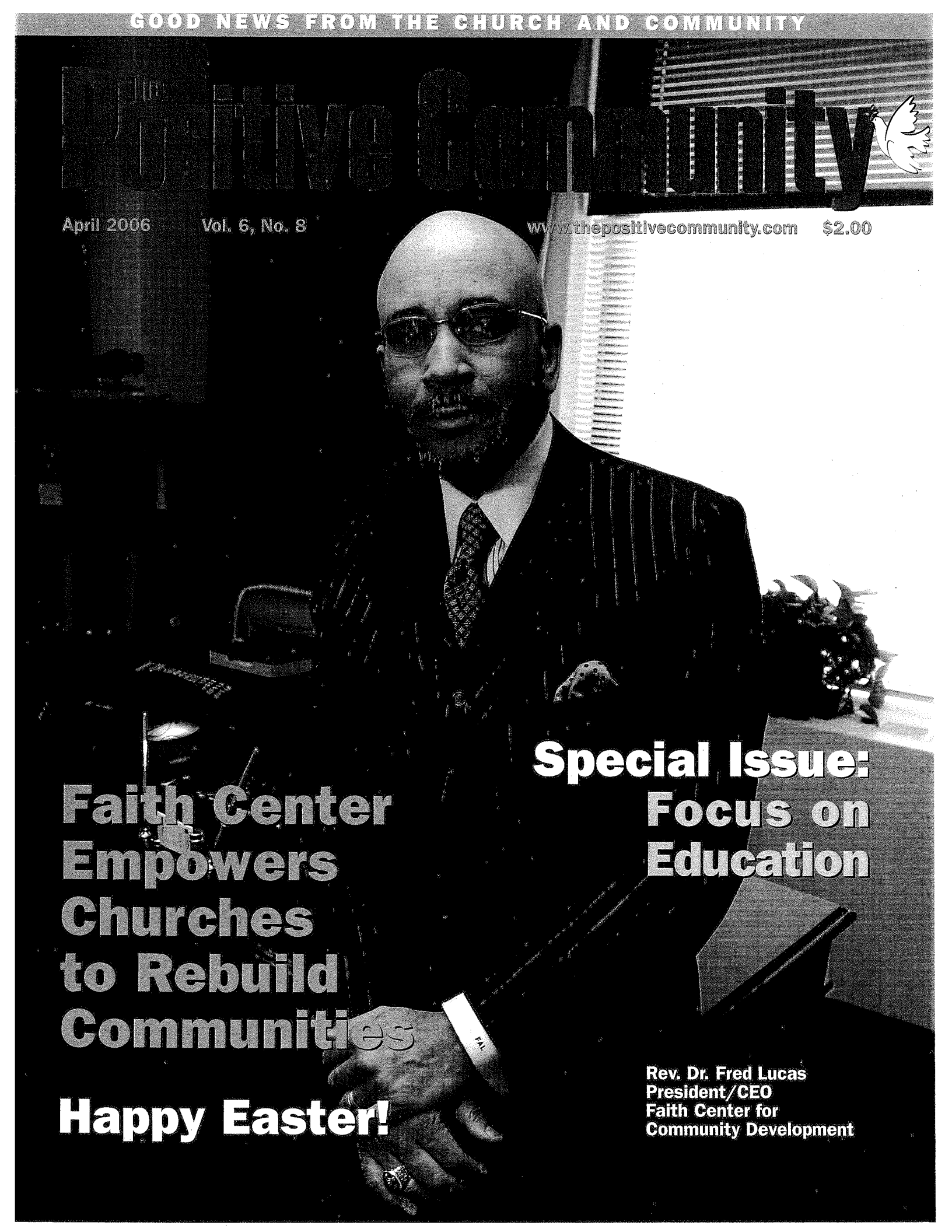
The study is funded by the U.S. Department of Defense Breast Cancer Research Program, one of the largest funders of breast cancer research in the country. The Department of Defense (DOD) peer-reviewed Breast Cancer Research Program (BCRP) was created in 1992 as a result of the National Breast Cancer Coalition's (NBCC) "$300 Million More" campaign, which was designed to increase federal funding for breast cancer research

For more information about enrolling in this study, please call 973-972-4383.

GOOD NEWS FROM THE CHURCH AND COMMUNITY

The Positive Community

April 2006 Vol. 6, No. 8 www.thepositivecommunity.com $2.00



Faith Center Empowers Churches to Rebuild Communities

Special Issue: Focus on Education

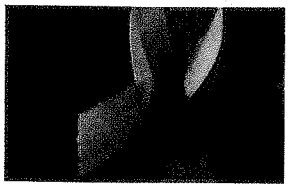
Happy Easter!

Rev. Dr. Fred Lucas
President/CEO
Faith Center for
Community Development

Breast Cancer Trial

UMDNJ Seeks African American Women for Culturally and Spiritually Centered Study

University News Service



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